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#### **REMARKS**

#### **Introductory Comments**

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 1-17 and 26 are pending and are under consideration. The specification and claims 1, 2, 3, 9, 14, 15, 16, 17 and 26 have been amended. No new matter has been added as a result of these amendments. Specifically, claims 3 and 11 have been amended to recited the chemical name for MERQUAT and claims 2 and 16 have been amended to correct a typographical error. Claims 1, 9, 14-17 and 26 have been amended to require the polycation to be in an unconjugated form and to explicitly require a step in the body of the claims for decreasing interferences as requested by the Examiner. Support for these amendments can be found in the specification on pages 2-4 and in the examples.

Applicants acknowledge with thanks the Examiner's withdrawal of the rejection under 35 U.S.C § 112, second paragraph made in the previous Office Action.

## Rejection of Claims 1-17 and 26 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-17 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Specifically, the Examiner states that MERQUAT is a compound which is a trademark and should be capitalized.

It appears that the Examiner means to object to the specification and the claims for the use of MERQUAT without a clear indication that it is a trademark, instead of rejecting the specification for a minor informality. Applicants would like to point out to the Examiner that the term MERQUAT is capitalized in both the

specification and in the claims. However, Applicants have amended the specification to specifically indicate that MERQUAT is a trademark and its chemical name is dimethyldiallylammonium chloride. Additionally, Applicants have amended claims 3 and 11 to recited the chemical name for MERQUAT instead. Support for the chemical name of MERQUAT can be found, for example, in U.S. Patent No. 6,251,145 at column 6, line 63 to column 7, line 7 and in U.S. Patent No. 6,224,852 at column 7, lines 6-12.

The Examiner also states that claims 1, 17 and 26 are missing a critical step because the preamble recites "A method for decreasing interferences which result in inaccurate reading in serum or plasma sample" but that the body of the claims fails to recite any step of decreasing the interferences in serum or plasma samples. Applicants respectfully traverse the rejection.

Applicants wish to point out to the Examiner that all of the pending claims are directed to a method instead of an apparatus or product. Thus, the preamble, which requires the method for decreasing interferences must be given weight as opposed to an apparatus or a product claim, where functional language may not be given weight in the preamble. However, in order to expedite prosecution, Applicants have amended the claims to specifically recite decreasing interferences in the body of the claims.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-17 and 26 under 35 U.S.C. § 112, second paragraph.

### Rejection of Claims 1-13 Under 35 U.S.C. § 102(e)

Claims 1-13 are rejected under 35 U.S.C. § 102(e) as being anticipated by Petry *et al.*, U.S. Patent No. 6,406,858 (herein Petry).

Specifically, the Examiner indicates that Petry meets all of the claim language. On page 9 of the Office Action, the Examiner states that Applicants' previous arguments are deemed unpersuasive since the claims use the "comprising" language and therefore the claims read on the use of other reagents or compounds in addition to the polycation. Applicants respectfully traverse the rejection.

As stated in Applicants' previous response, Petry's method uses at least two immunoreactants that specifically bind with separate epitopes of the analyte. Petry uses what is called a "scavenger conjugate" during the assay which comprises an enzyme <u>and</u> a protein or oligomer in order to reduce interaction of the unknown interference (column 2, lines 49-50). Applicants submit that there is nothing in Petry that teaches or suggests to one of ordinary skill in the art that a large polycation that is <u>not conjugated</u> to an enzyme can be used in a specific-binding assay to decrease interferences. Moreover, Petry teaches away from present invention. As discussed in Applicants' previous response, Petry, at column 2, lines 57-65, teaches only the combination of an enzyme <u>and</u> protein or polymer (therefore in a conjugated form) would reduce interferences. The use of complexes or a polycation in a conjugated or complexed form would affect the method of decreasing interferences because this would interfere with binding affinity and epitope availability.

In order to expedite prosecution, Applicants have amended the claims to require the large polycation to be in an unconjugated form. The Examiner's arguments appear to suggests that this language would overcome the rejection using Petry under 35 U.S.C. § 102 and place the claims in condition for allowance. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-13 under 35 U.S.C. § 102(e) as being anticipated by Petry *et al.*, U.S. Patent No. 6,406,858.

### Rejection of Claims 15-16 Under 35 U.S.C. § 103(a)

Claims 15-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Petry *et al.*, U.S. Patent No. 6,406,858 (herein Petry).

Specifically, the Examiner states that Petry's method is broad enough to encompass the detection of free prostate specific antigen to one of ordinary skill in the art. Applicants point out to the Examiner that the pending claims are directed toward a method instead of an apparatus or a product. Accordingly, every step of the claimed method, including the preamble, must be given weight. Absent a motivation, the rejection of claims 15-16 is deemed improper.

Additionally, Applicants have amended claims 15-16 to explicitly require the polycation to be in an unconjugated form, in order to overcome the rejection using Petry. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 15-16 under 35 U.S.C. § 103(a) as being unpatentable over Petry *et al.*, U.S. Patent No. 6,406,858.

Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Petry *et al.*, U.S. Patent No. 6,406,858 (herein Petry), further in view of Massey *et al.*, U.S. Patent No. 5,798,083 (herein Massey).

Specifically, the Examiner applied Massey as a teaching for acridinium as a chemiluminescent label. Applicants respectfully traverse the rejection.

The deficiencies of Petry have been discussed in detail above. Applicants herein incorporate by reference their arguments made previously. The deficiencies of Petry are not cured by Massey. Therefore, in view of the aforementioned arguments, Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. § 103(a).

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Petry *et al.*, U.S. Patent No. 6,406,858 (herein Petry), in view of Cantor, U.S. Patent No. 5,994,085 (herein Cantor) and further in view of Diamandis, U.S. Patent No. 5,688,658 (herein Diamandis).

Specifically, the Examiner applied Cantor as a teaching for detecting free prostate specific antigen and Diamandis for the teaching of using acridinium as a luminescent label. Applicants respectfully traverse the rejection.

The deficiencies of Petry have been discussed in detail above. Applicants herein incorporate by reference their arguments made previously. The deficiencies of Petry are not cured by Cantor nor Diamandis. Therefore, in view of the aforementioned arguments, Applicants respectfully request withdrawal of the rejection of claim 17 under 35 U.S.C. § 103(a).

Claim 26 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Petry *et al.*, U.S. Patent No. 6,406,858 (herein Petry), in view of Allard *et al.*, U.S. Patent No. 6,107,049 (herein Allard) and further in view of Diamandis, U.S. Patent No. 5,688,658 (herein Diamandis).

Specifically, the Examiner applied Allard as a teaching for detecting total prostate specific antigen and Diamandis for the teaching of using acridinium as a luminescent label. Applicants respectfully traverse the rejection.

The deficiencies of Petry have been discussed in detail above. Applicants herein incorporate by reference their arguments made previously. The deficiencies of Petry are not cured by Allard nor Diamandis. Therefore, in view of the aforementioned arguments, Applicants respectfully request withdrawal of the rejection of claim 26 under 35 U.S.C. § 103(a).

#### CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101, 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

R. Scoop, et al.

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